REMARKS:

Applicant has carefully studied the nonfinal Examiner's Action and all references cited therein. The amendment appearing above and these explanatory remarks are believed to be fully responsive to the Action. Accordingly, this important patent application is now believed to be in condition for allowance.

Applicant responds to the outstanding Action by centered headings that correspond to the centered headings employed by the Office, to ensure full response on the merits to each finding of the Office.

Claim Rejections – 35 U.S.C. § 103

Applicant acknowledges the quotation of 35 U.S.C § 103(a).

Claims 1-5, 9, 10, 12, 13 and 14 stand rejected under 35 U.S.C § 103(a) as being unpatentable over Giger et al. (U.S. 5,133,020) in view of Huo et al. (U.S. 6,282,305).

Regarding claim 1, the Office states that Giger et al. teaches identifying a standard threshold of the computer algorithm for identifying false positive abnormalities that is independent of the array of risk factors (column 6, lines 33-column 9, line 10); and adjusting the threshold for identifying false positives based on the risk associated with an asymptomatic patient (column 12, line 58-column 13, line 7). The Office goes on to state that while Giger et al. does not specifically teach calculating breast cancer risk, that Huo et al. discloses a method which includes establishing a risk probability with a patient with factors such as age (column 5, lines 55-63; column 6, lines 25-40); applying a computer algorithm to find abnormalities in a patient's mammogram (column 9, lines 30-48). The Office concludes that it would have been obvious for one of ordinary skill in the art at the time the invention was made to combine the references of Huo et al. with Giger et al. to gain the benefit of using known risk analysis methods to improve the prognosis or diagnosis of breast cancer based on mammograms. In support of the combination, the Office states that Giger et al. indicates that the threshold may be adjusted for the risk assessment of a patient for better evaluation of a mammogram (column 12, line 58-

column 13, line 7) and that based on their recommendation, one of ordinary skill in the art would be motivated to search for a method of calculating breast cancer risk. Huo et al. provides methods of calculating breast cancer risk. One of ordinary skill in the art would be motivated to combine the references of Giger et al. and Huo et al. in order to carry out Giger et al.'s method as he indicates.

Applicant respectfully traverses the finding of the Office.

Claim 1 is a method of screening an asymptomatic patient's mammogram to identify abnormalities, which includes the steps of: establishing a risk probability value associated with an asymptomatic patient, the risk probability value calculated from an array of risk factors associated with breast cancer; selecting a computer algorithm to identify abnormalities in the asymptomatic patient's mammogram; identifying a standard threshold of the computer algorithm for identifying false positive abnormalities, wherein the standard threshold is independent of the array of risk factors associated with the asymptomatic patient; adjusting the standard threshold of the computer algorithm for identifying false positive abnormalities in response to the risk probability value associated with the asymptomatic patient; applying the computer algorithm using the adjusted standard threshold to identify abnormalities in the asymptomatic patient's mammogram; and producing an electronic output image of the asymptomatic patient's mammogram that visualizes the identified abnormalities.

As claimed, the present invention is directed to a method of screening an asymptomatic patient's mammogram to identify abnormalities. As such, the mammogram of interest is a mammogram of an asymptomatic patient, i.e. a mammogram that has not yet been identified as having any abnormalities requiring further examination. This is typically referred to in the field as "primary detection" and is common in mass screenings.

Giger et al. describes at col. 4, lines 59 through column 10, line 3, a "primary detection" process in which asymptomatic patient's mammograms are analyzed to identify abnormalities. Giger et al. describes the use of threshold(s) and cutoff(s) in regard to this primary detection process. However, Giger et al. does not describe adjusting the threshold(s) or cutoff(s) during this primary detection process based on identified risk factors for the patient.

In addition, Giger et al. describes at col. 10, line 4 through col. 13, line 63, a "classification" process which is different than the "primary detection" process of Giger et al. described at col. 4, line 59 through col. 10, line 3. In the classification process of Giger et al., a suspicious region of the mammogram identified in the "primary detection" process is further analyzed to determine if the suspicious region is benign or malignant. Giger et al. does suggest adjusting the cutoff for high risk patients during the "classification" process at col. 12, line 66 through col. 13, line 4, as suggested by the Office. However, the suggestion to adjust the cutoff during the classification process of Giger et al. is not considered equivalent to a suggestion to adjust the cutoff during the detection process.

In other words, there are two processes described by Giger et al., a detection process and a classification process. In the detection process for identifying abnormalities in an asymptomatic patient's mammogram, Giger et al. describes the cutoff values as being fixed and Giger et al. does not teach or suggest adjusting the cutoff values during the detection process based on patient risk factors. In the classification process for classifiying an identified abnormality as being either benign or malignant, Giger et al. suggests that the cutoff values could be adjusted based on patient risk factors.

Claim 1 of the present invention is directed to a method of screening an asymptomatic patient's mammogram to identify abnormalities, and requires adjusting the standard threshold of the computer algorithm for identifying false positive abnormalities in response to a risk probability value associated with the asymptomatic patient.

Applicant contends that Giger et al. does not teach or suggest a method of screening an asymptomatic patient's mammogram to identify abnormalities, and requires adjusting the standard threshold of the computer algorithm for identifying false positive abnormalities in response to a risk probability value associated with the asymptomatic patient, but rather teaches a method of screening an asymptomatic patient's mammogram to identify abnormalities using a standard threshold that is *not* adjusted based on the patient's risk factors. Giger et al. only suggests adjusting the threshold during the classification process, not during the detection process of the abnormality.

In addition, the Office contends that it would have been obvious for one of ordinary skill in the art at the time the invention was made to combine the references of Huo et al. with Giger et al. to gain the benefit of using known risk analysis methods to improve the prognosis or diagnosis of breast cancer based on mammograms. In support of the combination, the Office states that Giger et al. indicates that the threshold may be adjusted for the risk assessment of a patient for better evaluation of a mammogram (column 12, line 58-column 13, line 7) and that based on their recommendation, one of ordinary skill in the art would be motivated to search for a method of calculating breast cancer risk. Huo et al. provides methods of calculating breast cancer risk. One of ordinary skill in the art would be motivated to combine the references of Giger et al. and Huo et al. in order to carry out Giger et al.'s method as he indicates.

Applicant respectfully disagrees with this finding by the Office.

As previously stated, the detection process of Giger et al. does not suggest varying the threshold values associated with the identification of abnormalities in an asymptomatic patient's mammogram based on the patient's risk factors. As such, there is no suggestion or motivation in either Giger et al. or Huo et al. to combine the method of establishing a breast cancer risk probability of Huo et al. with the detection method of Giger et al. to arrive at the invention, because Giger et al. does not suggesting varying the threshold values for primary detection purposes based on a patient's risk factors as suggested by the Office. While Giger et al. may suggest varying the threshold value for classification of the abnormality as being either malignant or benign based on patient risk factors, this is not equivalent to varying the threshold value for detection of the abnormality itself.

For the reasons cited above, Applicant believes that independent claims 1 and 14 are not obvious in view of Giger et al. in combination with Huo et al., and are therefore believed to be in condition for allowance.

Claims 2-7 and 9-13 are dependent upon claim 1, and are therefore allowable as a matter of law.

If the Office is not fully persuaded as to the merits of Applicant's position, or if an Examiner's Amendment would place the pending claims in condition for allowance, a telephone call to the undersigned is requested.

Very respectfully,

SMITH & HOPEN

By:_____

Molly Sauter
180 Pine Avenue North
Oldsmar, Florida 34677
(813) 925-8505
Agent for Applicant

Dated: September 8, 2008
Reg. No.: 46,457

CERTIFICATE OF ELECTRONIC TRANSMISSION

(37 C.F.R. 2.190 (b))

I HEREBY CERTIFY that this correspondence is being electronically transmitted to the Patent and Trademark Office through EFS Web on Sepember 8, 2008.

/erica gossage/

Date: September 8, 2008

Erica Gossage